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AUTHOR(S):

Yanagisawa, Hiromu; Saito, Naritatsu; Imai, Masao; Minakata, Kenji; Fujita, Takanari; Watanabe, Shin; Watanabe, Hirotoshi; ... Daijo, Hiroki; Sakata, Ryuzo; Kimura, Takeshi

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# **Successful Balloon Aortic Valvuloplasty as a Bridge Therapy to Transcatheter Aortic Valve Implantation during the Proctoring Period**

Hiromu Yanagisawa, MD<sup>1</sup>, Naritatsu Saito, MD<sup>1</sup>, Masao Imai, MD<sup>1</sup>, Kenji Minakata, MD<sup>2</sup>,  
Takanari Fujita, MD<sup>1</sup>, Shin Watanabe, MD<sup>1</sup>, Hirotoshi Watanabe, MD<sup>1</sup>, Kazuhiro  
Yamazaki, MD<sup>2</sup>, Toshiaki Toyota, MD<sup>1</sup>, Tomohiko Taniguchi, MD<sup>1</sup>, Junichi Tazaki, MD<sup>1</sup>,  
Satoshi Shizuta, MD<sup>1</sup>, Hiroki Daijo, MD<sup>3</sup>, Ryuzo Sakata, MD<sup>2</sup>, Takeshi Kimrui, MD<sup>1</sup>

1. Department of Cardiovascular Medicine, Graduate School of Medicine, Kyoto University, Kyoto, Japan
2. Department of Cardiovascular Surgery, Graduate School of Medicine, Kyoto University, Kyoto, Japan
3. Department of Anesthesiology, Graduate School of Medicine, Kyoto University, Kyoto, Japan

**Address for Correspondence:**

Naritatsu Saito

Department of Cardiovascular Medicine, Graduate School of Medicine, Kyoto University

54 Shogoin Kawahara-cho, Sakyo-ku, Kyoto 606-8507, Japan

E-mail: [naritatu@kuhp.kyoto-u.ac.jp](mailto:naritatu@kuhp.kyoto-u.ac.jp)

Tel: +81-75-751-3198, Fax: +81-75-751-3299

**Abstract, 199 words**

In Japan, Transcatheter aortic valve implantation (TAVI) with Edwards-SAPIEN XT valve started in October 2013. All institutions should undergo a proctoring period to perform TAVI independently. Balloon aortic valvuloplasty (BAV) as a bridge to TAVI during the proctoring period should be performed with caution to avoid severe aortic regurgitation (AR) because bailout TAVI is not possible. We present a case in which BAV was successfully performed as a bridge to TAVI during the proctoring period. The patient was an 85-year-old man with medically uncontrollable congestive heart failure

due to severe aortic valve stenosis. The aortic valve area was 0.60 cm<sup>2</sup> with a left ventricular ejection fraction of 20%. TAVI was considered a safe but high-risk strategy owing to the unstable hemodynamic condition. We chose BAV as a bridge therapy to TAVI. The aortic annulus diameter was 25.3 mm on computed tomography scans. We chose a 20-mm balloon catheter to avoid BAV-induced AR. BAV was performed successfully without any complications. Transfemoral TAVI was performed successfully 16 days after BAV using a 26-mm SAPIEN XT valve. The postoperative course was uneventful. The case demonstrated BAV as a bridge therapy to TAVI can be safely and effectively performed during the proctoring period.

### **Learning Objective: 69 words**

All institutions should undergo a proctoring period to start transcatheter aortic valve implantation (TAVI). Balloon aortic valvuloplasty (BAV) during the proctoring period should be performed with caution. The present case suggests that BAV as a bridge therapy to TAVI can be safely performed during the proctoring period. An accurate measurement of aortic annulus diameter and the use of an undersized balloon catheter might reduce the risk of BAV-related AR.

## Key Words

Balloon Aortic Valvuloplasty, Transcatheter Aortic Valve Implantation, Transcatheter Aortic Valve Replacement.

## Main Text

**Word Count 1392 words**

## Introduction

Staged treatment is often conducted for patients with severe aortic valve stenosis undergoing transcatheter aortic valve implantation (TAVI). Several studies have demonstrated the efficacy of balloon aortic valvuloplasty (BAV) as a bridge therapy to TAVI in very high-risk patients[1,2]. Compared with the past, BAV is currently conducted more frequently, with the introduction of TAVI[1,2]. One of the most serious complications after BAV is uncontrollable aortic regurgitation (AR), which often requires emergent surgical aortic valve replacement (SAVR) or TAVI[2–8]. In Japan, SAPIEN XT (Edwards Lifesciences Inc., Irvine, CA, USA) has just become commercially available at

limited centers in Japan. Therefore, TAVI is still in the introductory phase in most Japanese institutions. Before commencing TAVI, all institutions are required to undergo a proctoring period. Special care is required when conducting BAV as a bridge therapy during the proctoring period because bailout TAVI is not possible. Herein, we present a patient with severe symptomatic aortic valve stenosis who was successfully treated with BAV and percutaneous coronary intervention (PCI) to control congestive heart failure, followed by TAVI. The procedure was conducted during the proctoring period.

## Case Report

An 85-year-old man with mild exertional dyspnea was referred to our hospital for treatment of severe aortic stenosis. His brain natriuretic peptide (BNP) level was 911 pg/mL. Transthoracic echocardiography showed a severely calcified tricuspid aortic valve with a peak/mean transvalvular pressure gradient of 116/70 mm Hg, and valve area of 0.60 cm<sup>2</sup>. Left ventricular ejection fraction was 50% and trivial mitral regurgitation was observed. The patient had a history of PCI of the right and left circumflex coronary arteries and received dual antiplatelet therapy with aspirin (100 mg/day) and clopidogrel (75 mg/day). Coronary angiography revealed a moderate to

severe stenosis in the middle portion of the right coronary artery (RCA). SAVR plus coronary artery bypass grafting (CABG) or PCI plus TAVI was indicated for the patient. The Society of Thoracic Surgeons (STS) risk score calculated for SAVR plus CABG was 6.3%. However, the patient refused any invasive treatments, and he was discharged from the hospital. Therefore, medical therapy was continued in the outpatient clinic.

Three months later, the patient was readmitted to the hospital because of acute exacerbation of congestive heart failure. Transthoracic echocardiography revealed that the left ventricular function was significantly reduced, with an ejection fraction of 20%. Mild mitral regurgitation was also observed. Congestive heart failure worsened despite medical treatment that included intravenous administration of inotropes, diuretics, and vasodilators. The BNP level was elevated to 5985 pg/dL, and chest radiography showed severe pulmonary congestion, cardiomegaly, and bilateral pleural effusions (Figure 1A). The patient was deemed inoperable for SAVR plus CABG. The STS score was 12.5% at that time. TAVI was considered a possible but high-risk strategy owing to the unstable hemodynamic condition. We planned a staged procedure: first, BAV and PCI to stabilize the patient's condition followed by TAVI under safer conditions. This plan required approval by off-site proctors because our institution was still in the proctoring period. All

required data were sent to the proctors, and the plan was approved after detailed discussion.

After obtaining the approval of our institutional human ethics committee and the written informed consent, BAV and PCI were conducted under local anesthesia. Three introducer sheaths were placed: a 12-F introducer sheath in the left femoral artery, a 5-F introducer sheath in the right femoral artery, and a 7-F introducer sheath in the right femoral vein. First, we conducted right heart catheterization, which showed a mean right arterial pressure of 14 mm Hg, mean pulmonary arterial pressure of 36 mm Hg, and mean pulmonary wedge pressure of 31 mm Hg. Cardiac output, determined by using the Fick method, was 2.35 L/min (cardiac index =  $1.49 \text{ L} \cdot \text{min}^{-1} \cdot \text{m}^{-2}$ ). A 5-F Amplatz Left 1.0 diagnostic catheter and a 0.035-inch straight guidewire were used to cross the stenotic aortic valve. Simultaneous pressure tracing demonstrated a mean pressure gradient of 51 mm Hg across the aortic valve, and the aortic valve area was  $0.32 \text{ cm}^2$ , as calculated by using the Gorlin formula (Figure 2A). The aortic annulus diameter was approximately 25 mm on computed tomography scans (Figure 3). We chose a 20-mm Maxi-LD balloon catheter (Cordis Corporation/Johnson & Johnson, Bridgewater, NJ, USA) for BAV to avoid BAV-induced AR. After placing a 0.035-inch extra-stiff guidewire



in the left ventricle, the balloon catheter was delivered retrogradely, and inflation was conducted under rapid right ventricular pacing at a heart rate of 200 bpm (Figure 2B). Post-BAV simultaneous pressure tracing showed that the mean pressure gradient decreased to 14 mm Hg and the aortic valve area increased to 0.86 cm<sup>2</sup> (Figure 2C). Transthoracic echocardiography showed that the AR remained trivial. PCI for the RCA was subsequently performed. A 2.5-mm × 24-mm Promus premiere stent (Boston Scientific, USA) was implanted in the middle portion of the RCA. Both BAV and PCI were completed successfully without any complications.

The patient's symptoms and hemodynamic parameters improved significantly after BAV. In fact, the BNP level decreased, but remained high, at 2867 pg/mL. Chest radiography showed improvement of the congestive heart failure (Figure 1B). Transthoracic echocardiography showed that the mean/peak transvalvular pressure gradient decreased to 30/50 mm Hg. The left ventricular ejection fraction improved to 25% and mild mitral regurgitation remained. Transfemoral TAVI was performed 16 days after BAV, under supervision of the on-site proctor. An 18-Fr e-sheath was inserted from the left femoral artery after surgical cut down, with the patient under general anesthesia. The aortic valve was crossed with a 5-F Amplatz Left 1.0 diagnostic catheter and a

0.035-inch straight guidewire. Pre-dilatation was conducted with a 25-mm Maxi LD balloon catheter (Cordis/Johnson & Jonson, USA) under rapid pacing at 200 bpm after placing a 0.035-inch extra-stiff guidewire in the left ventricle. Then, a 26-mm SAPIEN XT valve was deployed using 2 cc overfilled deployment balloon under rapid pacing at 200 bpm. Transesophageal echocardiography demonstrated that the valve was implanted in the correct position with mild perivalvular leakage. The 18-F e-sheath was retracted, and the arteriotomy was closed. Figure 4 shows the fluoroscopic images during TAVI. All procedures were successfully completed, and no procedural complications occurred. The total procedure time from skin to skin was 110 minutes, and the total amount of contrast media was 90 mL.

Congestive heart failure improved remarkably after TAVI. The BNP level decreased to 745 pg/mL, and chest radiography showed no signs of congestive heart failure (Figure 1C). Transthoracic echocardiography performed 8 days after TAVI showed mild paravalvular regurgitation, a peak/mean transvalvular pressure gradient of 12/6 mm Hg, a valve area of 1.1 cm<sup>2</sup>. The left ventricular ejection fraction was 36% with trivial mitral regurgitation. The patient was discharged from the hospital 16 days after TAVI.

## Discussion

This is the first case report demonstrating that BAV as a bridge therapy to TAVI can be safely and effectively performed during the proctoring period. BAV-induced severe AR was avoided with the use of a smaller balloon catheter. The valve function and hemodynamic status improved after BAV, which provided a better patient condition for TAVI.

The indication of BAV has been limited in patients who are not good candidates for SAVR because restenosis almost inevitably occurs within a few months, and no clear survival advantage has been demonstrated[6,9].

However, BAV is currently used more commonly as a bridge therapy to TAVI. BAV provides better valve function and a more stable hemodynamic condition for a short period of time. Within this period, TAVI can be performed under safer conditions. Serious complications related to BAV include stroke, AR, cardiac tamponade, atrioventricular block, vascular complications, and death. When medically uncontrollable AR occurs after BAV, emergent surgical valve replacement or TAVI is required to rescue the patient. However, emergent TAVI is not an option during the proctoring period. BAV during the proctoring period should be performed with caution to avoid severe AR requiring surgical or percutaneous aortic valve replacement. Severe

AR after BAV is a rare but possible complication. The frequency of BAV-induced severe AR varies from 0 to 6%, but is approximately 1% on average[2–9]. Several studies recommended using smaller balloon catheter to avoid acute complications after BAV[7,8,10]. An accurate measurement of aortic annulus diameter with computed tomography and the use of an undersized balloon catheter might reduce the risk of BAV-related AR. In the present case, a 20-mm-diameter balloon catheter was employed despite an annulus diameter of 25.0 mm, and the post-BAV AR was trivial.

In summary, we present a case of severe aortic stenosis that was successfully treated with BAV and staged TAVI. The results suggest that BAV as a bridge therapy to TAVI can be safely and effectively performed during the proctoring period, with caution.

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## **Conflict of Interests**

The authors declare that they have no conflict of interest.

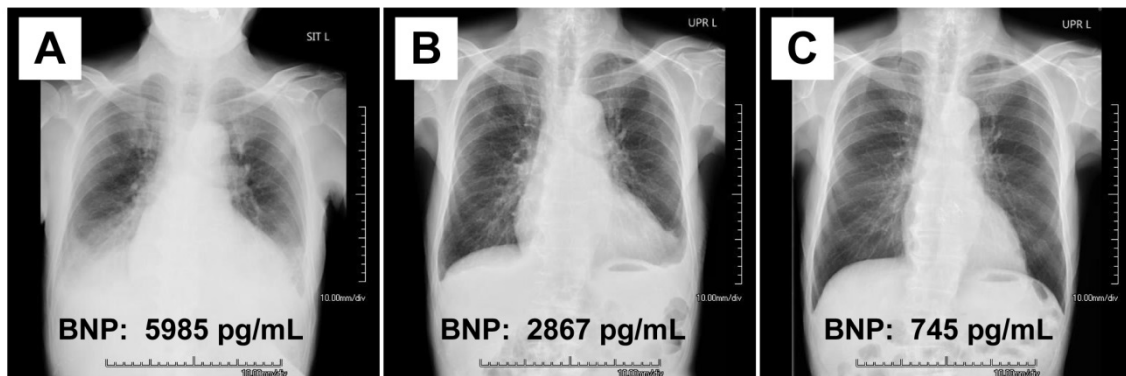
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## Figures Captions

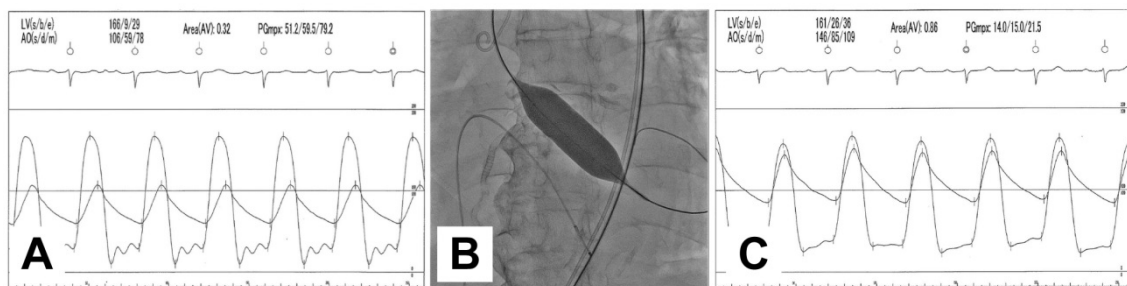
Figure 1



Changes on chest radiographs and in the brain natriuretic peptide (BNP) level. A, A chest radiograph before balloon aortic valvuloplasty (BAV) showing cardiomegaly, bilateral pleural effusions, and pulmonary congestion. B, A chest radiograph after BAV

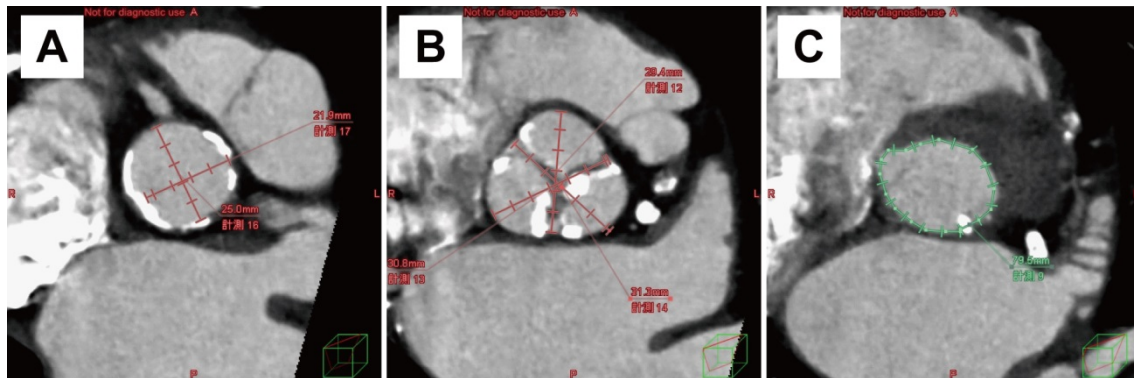
showing signs of improvement; no pleural effusion can be observed, but cardiomegaly and pulmonary are still present. C, The chest radiograph after transcatheter aortic valve implantation (TAVI) shows almost normal findings.

**Figure 2**



Fluoroscopic image during balloon aortic valvuloplasty (BAV) and simultaneous pressure tracings from the left ventricle and aorta. A, The pressure tracing before BAV showing a mean pressure gradient of 51 mm Hg and aortic valve area of 0.32 cm<sup>2</sup>. B, Balloon inflation with a 20-mm balloon catheter under rapid right ventricular pacing. C, The pressure tracing after BAV showing a mean pressure gradient of 14 mm Hg and aortic valve area of 0.86 cm<sup>2</sup>.

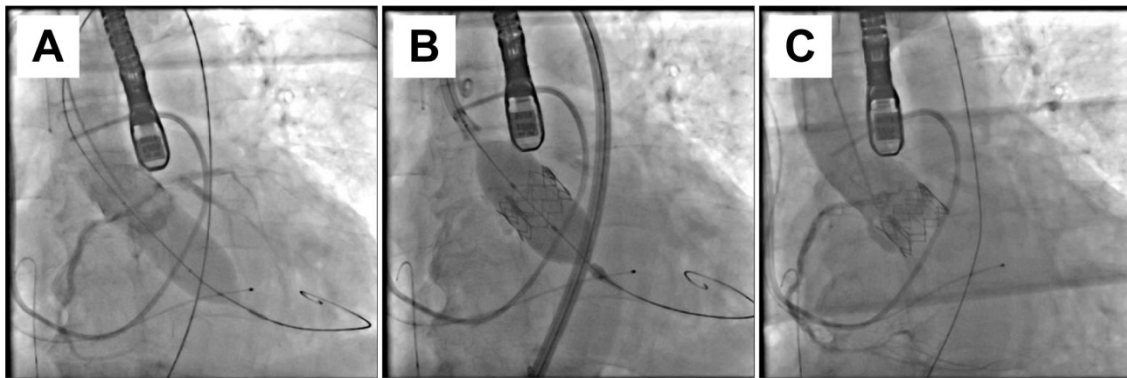
**Figure 3**



Computed tomography scans. A, Sinotubular junction diameter was 21.9 x 25.0 mm. B, Valsalva diameter was 29.4 x 30.8 x 31.3. Annulus diameter was approximately 25 mm; the average diameter was 25.9 mm (diameter: 22.5 x 29.2), the diameter calculated from the perimeter was 25.3 mm (perimeter: 79.5 mm), and the diameter calculated from the area was 24.9 mm (area: 488 mm<sup>2</sup>).

**Figure 4**





Fluoroscopic images during transcatheter aortic valve implantation (TAVI). A, An aortogram during pre-dilatation with a 25-mm balloon catheter showing trivial aortic regurgitation. B, Implantation of a 26-mm SAPIEN XT valve under rapid right ventricular pacing. C, The final aortogram showing mild aortic regurgitation and intact coronary arteries.